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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,641	06/16/2005	Charles C Hart	2836-USP-PCT-US	6610

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APPLIED MEDICAL RESOURCES CORPORATION
22872 Avenida Empresa
Rancho Santa Margarita, CA 92688

EXAMINER

RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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09/22/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,641	Applicant(s) HART, CHARLES C	
	Examiner Anu Ramana	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 8-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 7, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 8-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 26, the limitation "one of coplanar with and parallel to" renders the claim vague and indefinite. Is the surface coplanar or parallel or both? Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects

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for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 6, 8-11, 26-29 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sienkiewicz (US 5,656,012).

Sienkiewicz discloses a surgical retractor: including a malleable ring member (124a, 124b) with a plurality of links or bending portions; and a membrane fixedly attached to the ring member along a perimeter of the membrane; wherein the membrane is substantially taut in a low profile or flat configuration, defining a planar surface that is coplanar with a plane of the ring member. Sienkiewicz also discloses that the membrane is fabricated of surgical mesh, cloth, nylon or elastomeric material (Figs. 5-8, col. 4, line 14-35, col. 5, lines 41-67, col. 6 and col. 7, lines 1-10).

The method steps of claims 26-29 are inherently performed when the Sienkiewicz retractor is used to manipulate tissues during surgical procedures.

Claims 1-6, 8-9, 11 and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Boschetti (US 4,497,317).

Boschetti discloses a device including a malleable ring member 4 and a membrane or bag 2 fixedly attached to a perimeter of the ring member wherein the bag is made of a membrane of cotton, a bias woven fabric (Figs. 1, 3 and 4, col. 2, lines 65-68, col. 3 and col. 4, lines 1-63).

It is noted that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).

Claims 1-6, 8, 19-20 and 26-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kindberg et al. (US 5,143,082), as evidenced by Ellman (US 4,428,375).

Kindberg et al. disclose a surgical device to temporarily reposition body tissues and organs including a ring member having cords 20 and a membrane 15 made of a flexible material that could be a mesh structure (Figs. 1-3, col. 2, lines 56-68, col. 3 and col. 4, lines 1-56).

Kindberg et al. refer to Ellman for examples of pliable surgical materials having a mesh structure. Ellman discloses a mesh construction with woven or knitted strands (see col. 2, lines 18-68 of Ellman).

The method steps of claim 26-29 are inherently performed when the Kindberg et al. device is used to reposition organs during a surgical procedure.

Claims 1, 3-6, 8-13, 26-27 and 29-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Rambo (US 6,450,983).

Rambo discloses a retraction device with a malleable ring member 10 and a "substantially taut" flexible sleeve or membrane 8 attached to a perimeter of the ring wherein the membrane is made from an elastic material (Figs. 1, 6-9, 16, 18, 40-41, 63 and 66, col. 6, lines 3-67, cols. 7-8 and col. 9, lines 1-33).

Regarding the limitation, "positioned across the ring member," it is the Examiner's position that membrane 8 of Rambo covers the ring member and is thus positioned across the ring member, in that it extends from an inside surface of the ring member to the opposite, outside surface of the ring member.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sienkiewicz (US 5,656,012) in view of Bonutti (US 5,163,949).

Sienkiewicz discloses all elements of the claimed invention except for the retractor being made of a transparent material.

It is well known in the art to construct a retractor of a transparent material for better visibility.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the Sienkiewicz retractor of a transparent material, as taught by Bonutti, for better visibility.

Claims 2, 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rambo (US 6,450,983) in view of Berman (US 5,899,942).

Rambo discloses all elements of the claimed invention except for a membrane made of bias woven or knitted fabric.

Berman teaches a medically acceptable barrier or membrane material made of a knit or woven polyester fabric (col. 3, lines 52-67 and col. 4, lines 1-12).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed membrane 8 of Rambo of a knit or woven polyester fabric, as taught by Berman, since it was well known in the art to use a woven polyester fabric as a medically acceptable material that is impermeable to tissue and debris.

Claims 14-25 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rambo (US 6,450,983) in view of Balsells (US 5,161,806).

The combination of Rambo and Berman discloses all elements of the claimed invention except for a reinforcement member in the ring to adjust the flexibility of the ring.

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It is well known to modify the flexibility of a hollow ring by reinforcing the ring using a metallic component (14) embedded in a plastic component as demonstrated by Balsells (col. 2, lines 1-12).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a selectively malleable ring in the device of Rambo by providing a hollow ring with reinforcement, as demonstrated by Balsells, since it was well known in the art to provide reinforcement in a hollow ring to change its malleability.

The method steps of claims 32-34 are rendered obvious by the above discussion.

Response to Arguments

Applicant's arguments submitted under "REMARKS" in the response filed on July 7, 2008 have been fully considered but are not persuasive for the following reasons.

Applicant's arguments, with respect to the rejections of claims 1-6, 8, 9 and 11 over Boschetti, are not persuasive for the following reason.

The Examiner reiterates that the limitation, "substantially taut" only requires some portions of the membrane to be taut and does not imply that there can be no slack. Fig. 3 of Boschetti clearly shows the membrane to be stretched across the ring member and "substantially taut."

Applicant's arguments with respect to the rejections of claims 1-6, 8, 19, 20 and 26-29 under 35 USC 102(b) as being anticipated by Kindberg et al. as evidenced by Ellman are not persuasive for the following reason.

The Examiner reiterates that the limitation, "substantially taut" only requires some portions of the membrane to be taut and does not imply that there can be no slack. Membrane 15 covers the ring member and meets the limitation "across the ring member" since this limitation requires the membrane to go from one side to another

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side of the ring member. Figure 2 clearly shows the membrane to be "substantially taut" in a low-profile configuration.

Applicant's arguments, with respect to the rejections under 35 USC 102(e) over Rambo, are not persuasive for the following reasons.

In a low-profile or rolled-up configuration, sleeve 8 defines a planar surface, i.e., at least one planar surface, that is coplanar with the plane of the ring member. Contrary to Applicant's arguments, the examiner notes that the claim language does not preclude a cylindrical configuration as shown in Rambo. The Rambo device could be compressed such that the membrane is positioned across the ring member.

The Examiner suggests language such as "a membrane having a planar top surface and a planar bottom surface and an outer perimeter wherein the ring is attached to one of the top surface of the membrane or the bottom surface of the membrane such that the membrane stretches across the ring member" to overcome the separate rejections over Boschetti, Kindberg et al. and Rambo.

Notwithstanding the above, the Examiner has introduced new grounds of rejection in this action.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
September 15, 2008

/Anu Ramana/
Primary Examiner, Art Unit 3733